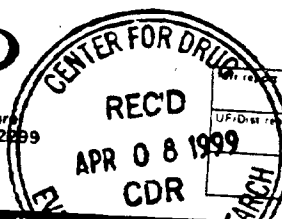


McNeil
Consumer Healthcare
Neil Consumer Healthcare
Washington, PA 19034-2299



Approved by FDA on 11/15/97

Page ____ of ____

A. Patient information

1. Patient identifier 614048 In confidence	2. Age at time of event: 37 yrs Date of birth: [redacted]	3. Sex () female (X) male	4. Weight unk lbs or kgs
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B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- | | |
|--|--|
| () death (mo/day/yr) | () disability |
| () life-threatening | () congenital anomaly |
| (X) hospitalization - initial or prolonged | () required intervention to prevent permanent impairment/damage |
| () other: | |

3. Date of event

3/4/95
(mo/day/yr)

4. Date of this report

04/05/99
(mo/day/yr)

5. Describe event or problem

Notification via litigation of case summaries provided by physician/co-author of literature report (N Engl J Med 1997;337:1112-7). Medical records provided of pts hospitalized for acetaminophen ingestion b/t 1/1/92 & 4/30/95. Med records indicate a 37 yo w/ h/o multi-drug abuse presented to hosp on 3/3/95 w/ 3 day h/o FEVER, CHILLS, HEADACHE, assoc with RUQ and mid epigastric pain (ABDOMINAL PAIN). One to two days PTA, developed N/V, ANOREXIA/malaise, progressing to coffee grounds x5. Pt also reported dark urine (URINE ABNORMALITY). Pt had been drinking 2 fifths etoh/wk & beer for 3 months PTA. Pt denied excessive TYLENOL use. He ran out of TYLENOL #4 one month ago-may have taken some Extra Strength TYLENOL-he was not sure. Pt does report chronic NSAID use but unable to quantitate amt. Liver US revealed HEPATITIS & serologies found infectious HBV & HCV. Tx included FFP, ZANTAC®, & MUCOMYST®. EGD revealed esophagitis, duodenitis, hiatal hernia & portal HTN gastropathy. Pt placed on omeprazole. (See Sec C10)

6. Relevant tests/laboratory data, including dates

3/3/95 (2350)AST=10530,ALT=6360,AP=217,Tbili=5.4,TP=6.7,xlb=3.6,GGT=503;3/4/95(0700)pH=7.47,PCO2=40,PO2=69,HCO3=29,O2Sat=94;(1140)PT=23.0,PTT=39.7,APAP=less than 1,salic=less than 1 cocaine & metab;trimethoprim detected in urine, (See Sec 87)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

5/5/87 admitted to hosp s/p OD on 30 TYLENOL® #3 & 15 TRANXENE®; previous suicide attempts, gastritis, hiatal hernia, asthma, scoliosis, depression, h/o drug abuse: cocaine, heroin, hx of addiction to TYLENOL® #3 & #4, IVDA (cocaine last used 2 weeks ago), ETOH (last drink 3/3/95) (Sec B6 cont)etoh=(-);HBSAG,a-HBc,a-HBc IgM,a-HCV (reactive)

C. Suspect medication(s)

1. Name (give labeled strength, if known)

- #1 possibly Extra Strength TYLENOL®
#2 unk NSAID possibly ibuprofen (See also Sect C10)

2. Dose, frequency & route used

- #1 may have taken some
#2 unknown

3. Therapy dates (if unknown, give duration) from/to (or best estimate):

- #1 unknown dates or duration
#2 unknown

4. Diagnosis for use (indication)

- #1 pain
#2 back pain

5. Event abated after use stopped or dose reduced

- #1 () Yes () No (X) N/A

- #2 () Yes () No (X) N/A

8. Event reappeared after reintroduction

- #1 () Yes () No (X) N/A

- #2 () Yes () No (X) N/A

10. Concomitant medical products and therapy dates (exclude treatment of event) THEO-DUR®, PROVENTIL®, SOMA®, BACTRIM®, (Sec C1 cont):TYLENOL® #4(last dose 3-4 wks prior);(Sec B5 cont):Pt d/c'd 3/11/95 clinically improved w/LFT's beginning to normalize. Prin dx: UGI bleed (HEMORRHAGE GI) & acute viral hepatitis (HBV-HCV).

G. All manufacturers

1. Contact office - name/address (& mfring facilities, if known)

McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number

215-273-7820

3. Report source (check all that apply)

- () foreign
() study
() literature
() consumer

- (X) health professional
() user facility

- () company representative
() distributor
() other:

4. Date received by manufacturer (mo/day/yr)

03/29/99

6. If IND, protocol #

7. Type of report (check all that apply)

- () 5-day (X) 15-day
() 10-day () periodic
(X) Initial () follow-up #

9. Mfr. report number

1153613A

(A) NDA # 19-872

IND #

PLA #

pre-1938 () Yes

OTC product (X) Yes

8. Adverse event term(s)

CHILLS FEVER HEADACHE
PAIN ABDOMINAL NAUSEA VOMIT
ANOREXIA URINE ABNORMAL
HEPATITIS HEMORRHAGE GI

E. Initial reporter

1. Name, address & phone #

[redacted] MD & [redacted]
[redacted] Medical Ctr
[redacted] Boulevard
[redacted]

2. Health professional?

(X) Yes () No

3. Occupation

physician

4. Initial reporter also sent report to FDA

() Yes () No (X) Unk



Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.